DETAILED ACTION

Claims 1-17 and 21-33 are presented for examination.

The Amendments and Remarks, filed April 14, 2008, have been received and entered into the application.

Applicant's arguments, filed April 14, 2008, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

The Finality of the previous office action, mailed 12/13/07, is withdrawn. Also, the Notice of Appeal, filed 4/14/08, is deemed moot due to the below new grounds of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 13-17, 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (US Patent No. 6596298 B2), in view of Oppenheimer et al. (US Patent No. 4980169), taken with Damani et al. and further in view of Babich et al. (US Patent No. 6395299 B1).

Leung et al. teach physiologically acceptable films, including edible films, are disclosed. The films include a water soluble film-forming polymer such as pullulan. Edible films are disclosed that include pullulan and antimicrobially effective amounts of the essential oils thymol, methyl salicylate, eucalyptol and menthol. The edible films are effective at killing the plaque-producing germs that cause dental plaque, gingivitis and bad breath. The film can also contain pharmaceutically active agents. Methods for producing the films are also disclosed (see abstract). In a second embodiment of the invention, the rapidly dissolvable film acts as a vehicle for administering a pharmaceutically active agent orally, through a mucous membrane or an open wound of a patient (see col. 3, lines 8-11). The invention is also directed to a method for producing a supple, non-self-adhering film especially suitable for oral delivery. The method comprises mixing a film forming agent and at least one stabilizing agent to

provide a film-forming mixture; dissolving water-soluble ingredients in water to provide an aqueous solution; combining the film-forming mixture and the aqueous solution to provide a hydrated polymer gel; mixing oils to form an oil mixture; adding the oil mixture to the hydrated polymer gel and mixing to provide a uniform emulsified gel; casting the uniform gel on a substrate; and drying the cast gel to provide a film (see col. 3, lines 12-22). The film-forming agent used in the films according to the present invention can be selected from the group consisting of pullulan, **hydroxypropylmethyl cellulose**, **hydroxyethyl cellulose**, **hydroxypropyl cellulose**, **polyvinyl pyrrolidone**, **carboxymethyl cellulose**, **polyvinyl alcohol**, sodium alginate, polyethylene glycol, **xanthan gum**, tragacanth gum, guar gum, **acacia gum**, **arabic gum**, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl polymer, amylose, high amylose starch, hydroxypropylated high amylose starch, **dextrin**, pectin, **chitin**, **chitosan**, levan, elsinan, collagen, **gelatin**, **zein**, gluten, soy protein isolate, **whey protein** isolate, casein and mixtures thereof. A preferred film former is pullulan, in amounts ranging from about 0.01 to about 99 wt %, preferably about 30 to about 80 wt %, more preferably from about 45 to about 70 wt % of the film and even more preferably from about 60 to about 65 wt % of the film (col. 4, lines 64-67 & col. 5, lines 1-13). Suitable sweeteners that can be included are those well known in the art, including both natural and artificial sweeteners. Suitable sweeteners include, e.g.: A. water-soluble sweetening agents such as monosaccharides, disaccharides and polysaccharides such as xylose, ribose, glucose (dextrose), mannose, galactose, **fructose** (levulose), sucrose (sugar), maltose, invert sugar (a mixture of fructose and

glucose derived from sucrose), partially hydrolyzed starch, corn syrup solids (see col. 6, lines 25-32).

Oppenheimer et al. teach the present invention relates to improved formulations for confections which are intended to reside in the oral cavity for a period of time while being consumed. In particular, the present invention provides, among other things, medicinal tablets with enhanced flavored delivery as the confection dissolves in the oral cavity (see col. 1, lines 6-11). Confections, especially medicinal tablets which deliver active ingredients in the oral cavity, are well known in the art and may be divided into various classes based upon their composition or intended effect. Examples include lozenges, compressed tablets and other medicinal tablets. The confections may have breath fresheners, breath deodorants, cough suppressants, nasal **decongestants** and the like (see col. 1, lines 12-19). Enhancing the impact of the volatile oils in the oral cavity increases the benefit of the confection by ameliorating perceived bitterness, pungency, or other undesirable organoleptic sensations (col. 1, lines 33-36). Menthol is isolated principally from the oil of Mentha arvensis. In its commercial form, **menthol is present as crystals** obtained from a process involving cooling of the above mentioned oil. Fractional distillation of peppermint oil which usually contains from about **50% to about 65%** menthol provides another important source of menthol. In addition, menthol can be provided synthetically (see col.1, lines 37-44). The use of menthol, for example, for its medicinal effect is known in the art. Menthol's cooling effect to the mouth is useful to relieve local irritations in the throat and mouth (see col.1, lines 45-48). Eucalyptus is

another essential oil often combined with other **essential oils** such as menthol in confection formulations to impart medicinal effect. In particular, **eucalyptus** is believed to exhibit an expectorant action. The combination of the essential oils of menthol and eucalyptus, in a formulation capable of dissolving in the oral cavity provide a useful medicinal preparation in treatment of coughs and minor mouth, throat, and upper respiratory irritations (see col. 1, lines 49-57). Confections which include such medicinal formulations are cough drops, lozenges, etc. (see col. 1, lines 58-59). In a preferred embodiment, the confection contains both menthol and eucalyptus as the volatile oil component. In this embodiment, the confection confers medicinal benefits by providing active ingredients which relieve irritations of the nasopharyngeal region caused by coughing as well as providing a decongestant effect in the nasal cavity by vapor action released from the confection (see col. 4, lines 14-23). L-menthol and eucalyptus oil may be combined to provide the volatile oil component of the confection. When so combined, the menthol-eucalyptus is useful as an adjunct to coughing cold therapy (col. 8, lines 12-15). There are no teachings of surfactant, plasticizer, and polyalcohol in this composition. Therefore, Oppenheimer et al. teach a composition for decongestant free of surfactant, plasticizer, and polyalcohol.

Damani et al. teach pharmaceuticals for oral ingestion can take many different forms, such as liquids, emulsions, suspensions, aerosol sprays, solid capsules or tablets. Many pharmaceutical compositions including **oral decongestants** contain unpalatable ingredients and are therefore marketed in the form of liquids and sprays.

Pharmaceutical compositions in the form of **tablets or capsules which are intended to be swallowed** whole are also widely marketed. Taste-masking of the active ingredients contained in such products can be effected by covering the tablet with a thin and quickly dissolving coating, for example, using a gelatin outer shell in order to retain the active ingredient until the tablet has been swallowed. Alternatively, the tablet can be compressed sufficiently so that it stays intact for the short time that it is in the mouth (col. 1, lines 15-29). Suitable flavouring agents include an aromatic flavouring agent selected from menthol, peppermint oil, camphor, eucalyptol, **eucalyptus oil**, preferably Menthol (see col. 4, lines 15-17).

Babich et al. teach the prodrugs and/or matrices may, if desired, be presented in a pack or dispenser device which may contain one or more unit dosage forms containing the active ingredient. The pack may for example comprise **metal** or plastic **foil**, such as a blister pack. The pack or dispenser device may be accompanied by instructions for administration (see col. 59, lines 14-19).

Clearly, one having ordinary skill in the art would have been motivated to use the teachings of Leung et al. for the preparation of a rapidly dissolvable film which acts as a vehicle for administering a pharmaceutically active agent orally. Leung et al. and Oppenheimer et al. along with the teachings of Babich et al. for the packaging and enclosure of the product teach the composition. As combined, the teachings of Leung et al. for making an orally consumable films taken with the teachings teachings of Oppenheimer et al. for using volatile oil such as eucalyptus oil and flavor enhancing in

cough drops, and the packaging of the product taught by Babich et al., result in the claimed invention.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the teachings of the above references and produce a film delivery system for volatile decongestants.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Response to Arguments

Applicant argues that Leung does not disclose the use of polydextrose in a water-soluble film forming matrix in edible films. Examiner does not agree Leung et al. teach a water soluble film-forming polymer such as pullulan (see abstract) that contains polysaccharides such as dextrose (see col. 6, lines 25-32) and also dextrin. Dextrins are a group of low molecular weight carbohydrates produced by the hydrolysis of starch. Polydextrose is a group of polysacchrides made up of dextrin that is taught by Leung et al. in its orally consumable films.

Leung et al. clearly teach a water-soluble film comprising polydextrose. In obviousness rejection a combination of references is used, and the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the

combination of the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725(CCPA 1968); *In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981).*

Moreover, it is noted that rejections under 35 U.S.C. 103(a) are based on combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner October 22, 2008
1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614